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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,064	12/11/2003	Alexander Sulakvelidze	62610.000044	7824
21967	7590	06/04/2007	EXAMINER	
HUNTON & WILLIAMS LLP			KINSEY, NICOLE	
INTELLECTUAL PROPERTY DEPARTMENT			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/733,064	SULAKVELIDZE ET AL.
	Examiner	Art Unit
	Nicole E. Kinsey, Ph.D.	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 April 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 40-48 and 88-93 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 40-48 and 88-93 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.
_____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-42 remain rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (U.S. Patent No. 2,851,006). This rejection also applies to new claims 90-93.

Taylor et al. discloses submerging fertilized eggs infected with *Salmonella* into a fluid containing bacteriophages to free the eggs of bacteria (see entire document). Taylor et al. also discloses using a cocktail of different phages (col. 2, lines 25-44).

Applicants argue that Taylor et al. is limited to methods of introducing bacteriophages into an egg for the purpose of increasing the percentage of hatched birds, which is different from the claimed purpose (a method of poultry processing sanitation). This is not found persuasive.

Taylor et al. discloses submerging infected eggs into a solution of bacteriophage. In particular, Example I demonstrates the infection of eggs by submerging the eggs in a chilled culture of *Salmonella chittagong* for 10 minutes and then submerging the infected eggs in a polyvalent *Salmonella* phage containing liquid for 10 minutes. Clearly, any bacteria on the egg will be killed by the phage.

With regard to applicants' statement that Taylor et al. does not teach a method of poultry processing sanitation, the recitation " a method of poultry processing sanitation" is an intended use of the process. A recitation of intended use of the claimed invention must result in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitations. See *In re Casey*, 152 USPQ 235 (CCPA1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963). Here, the method of Taylor et al. (applying phage to an egg) is capable of performing the intended use of the instant claims. Therefore, Taylor et al. meets the claim limitations.

Claims 46-48 remain rejected under 35 U.S.C. 102(b) as being anticipated by Day et al. (U.S. Patent No. 4,851,240).

Day et al. discloses liquid preparation of at least two varieties of bacteriophage, which may be a formulation of phage in food or drinking water, for administering to livestock (see col. 5, line 41 to col. 6, line 5). It is common knowledge that chickens are livestock (The Cambridge Dictionary of American English defines livestock as "animals kept on a farm, such as cows, sheep, chickens, and pigs.") The phage formulations are for the prevention and treatment of microbial infestations.

Applicants argue that Day et al. is directed to a method of controlling bacterial growth in fermented animal food stock, especially silage, for feeding ruminant livestock,

which is different from the claimed purpose (a method of poultry processing sanitation).

This is not found persuasive.

Day et al. states that the liquid preparations are suitable for use in the preparation of cheese, spraying on silage, or administration to livestock (see col. 5, lines 45-58). As stated above, according to The Cambridge Dictionary of American English, chickens are livestock. Further, the phage preparation can be administered to livestock in drinking water (see col. 6, lines 1-6).

With regard to applicants' statement that Day et al. does not teach a method of poultry processing sanitation, the recitation "a method of poultry processing sanitation" is an intended use of the process. A recitation of intended use of the claimed invention must result in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitations. See *In re Casey*, 152 USPQ 235 (CCPA1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963). Here, the method of Day et al. (administering drinking water containing a mixture of phage to livestock including chickens) is capable of performing the intended use of the instant claims (sanitizing poultry). Therefore, Day et al. meets the claim limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-45 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Merril et al. (U.S. Patent No. 5,811,093) in view of Taylor et al. (U.S. Patent No. 2,851,006) as evidenced by Holzman. This rejection also applies to new claims 88 and 89.

Merril et al. discloses topically treating animals (e.g., man, domestic pets, livestock, pisciculture, and animals in zoos and aquatic parks) with composition comprising bacteriophages to kill bacteria (see col. 9, line 42 to col. 11, line 3). It is common knowledge that chickens, including newly hatched chicks, are livestock (The Cambridge Dictionary of American English defines livestock as "animals kept on a farm, such as cows, sheep, chickens, and pigs.") The phage formulations are for the prevention and treatment of bacterial infection in humans and animals.

Merril et al. does not disclose the use of a cocktail of phages. However, Taylor et al. discloses submerging fertilized eggs infected with *Salmonella* into a fluid containing bacteriophages to free the eggs of bacteria (see entire document). Taylor et al. also discloses using a cocktail of different phages (col. 2, lines 25-44).

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Merril et al. to use a cocktail of phages. One would have been motivated to do so, given the suggestion by Taylor et al. that cocktails of phages should be used to assure the destruction of all possible species of bacteria, namely *Salmonella* (col. 2, lines 25-44). There would have been a reasonable expectation of success given the knowledge that phages kill bacteria and also given the knowledge that more than one strain or species of bacteria can contaminate/infect an animal. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicants argue that Merril et al. does not teach a method of poultry processing sanitation. Applicants further argue that there is no motivation to select a freshly hatched chick or to apply the phage topically. This is not found persuasive.

It is common knowledge that poultry (live or processed) is contaminated with bacteria, in particular *Salmonella*. This is evidenced by Taylor et al.(col. 1, lines 1-51) and Holzman. Holzman discloses using phages to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs, and *E. coli* 0157, as a way of potentially clearing the poultry yards of *S. enteriditis*. Holzman states that "[u]p to 75% of human cases are acquired from meat, poultry or eggs, and up to 25% of broiler

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chickens and 18% of turkey carry that organism." (see page 48 of Holzman). Therefore, based on the common knowledge that chickens of all ages and types are contaminated/infected with Salmonella, one would be motivated to use the method of Merrill et al. and apply phages topically to chicks and chickens.

With regard to applicants' statement that Merril et al. does not teach a method of poultry processing sanitation, the recitation " a method of poultry processing sanitation" is an intended use of the process. A recitation of intended use of the claimed invention must result in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitations. See *In re Casey*, 152 USPQ 235 (CCPA1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963). Here, the combination of the methods of Merril et al. and Taylor et al. (administering a phage cocktail topically to livestock including chickens) is capable of performing the intended use of the instant claims (sanitizing poultry). Therefore, the combination of Merril et al. and Taylor et al. meets the claim limitations.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Nicole E. Kinsey, Ph.D.
Examiner
Art Unit 1648

/nk/

/Stacy B. Chen/ 5-30-2007
Primary Examiner, TC1600